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Proposed Re-evaluation Decision

Naphthalene Acetates

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Overview

After a re-evaluation of the naphthalene acetates, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing naphthalene acetates for the sale and use in Canada.

An evaluation of available scientific information found that products containing naphthalene acetates do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of naphthalene acetates uses, new risk-reduction measures must be included on the labels of all products.

Naphthalene acetic acid, its salts, and acetamide are chemicals collectively referred to as naphthalene acetates in this review because they are structurally related and are metabolized to the acid form. Thus, all references to application rate are in the unit of acid equivalent per hectare (a.e./ha). It should be noted that this family of active ingredients belongs to the arylacetic acid group and should not to be confused with naphthalene, which belongs to the aromatic hydrocarbon group. The re-evaluation of naphthalene will be addressed separately.

This proposal affects all end-use products containing naphthalene acetates registered in Canada. Once the final re-evaluation decision is made, the registrants will be instructed on how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for naphthalene acetates and presents the reasons for the proposed re-evaluation decision. It also proposes additional risk-reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of naphthalene acetates.

The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Naphthalene acetates, one of the active ingredients in the current re-evaluation cycle, have been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian re-evaluation decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

Given the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA will propose a re-evaluation decision and appropriate risk-reduction measures for Canadian uses of an active ingredient. In this decision, the PMRA takes into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

Based on the health and environmental risk assessments published in the 2007 RED, the USEPA concluded that naphthalene acetates were eligible for reregistration provided risk-reduction measures were adopted. The PMRA compared the American and Canadian use patterns and found the USEPA assessments described in this RED were an adequate basis for the proposed Canadian re-evaluation decision.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

What Are Naphthalene Acetates?

Naphthalene acetates are plant growth regulators due to their structural similarity to the natural plant growth hormone auxin, indole acetic acid. Auxin promotes growth in excised plant organs, induces adventitious roots, inhibits axillary bud growth and regulates gravitropism. Naphthalene acetates are used to delay flower induction and prevent preharvest fruit drop in orchard and ornamental trees.

Health Considerations

Can Approved Uses of Naphthalene Acetates Affect Human Health?

Naphthalene acetates are unlikely to affect your health when used according to the revised label directions.

People could be exposed to naphthalene acetates by consuming food and water, by working as a mixer/loader/applicator or by entering treated sites. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that naphthalene acetates were unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Maximum Residue Limits

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in/on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Naphthalene acetates are currently registered in Canada for use on apples and pears and could be used in other countries on crops that are imported into Canada. No specific MRLs have been established for naphthalene acetates in Canada. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. However, changes to this general MRL may be implemented in the future, as indicated in the Discussion Document DIS2006-01, *Revocation of the 0.1 ppm as a General Maximum Residue Limit for Food Pesticide Residues [Regulation B.15.002(1)]*. If and when the general MRL is revoked, a transition strategy will be established to allow permanent MRLs to be set.

Environmental Considerations

What Happens When Naphthalene Acetates Are Introduced Into the Environment?

Naphthalene acetates are unlikely to affect non-target organisms when used according to the revised label directions.

Environmental risk is assessed by the risk quotient method—the ratio of the estimated environmental concentration to the relevant effects endpoint of concern. The resulting risk quotients are compared to corresponding levels of concern. A risk quotient less than the level of concern is considered a negligible risk to non-target organisms, whereas a risk quotient greater than the level of concern indicates some degree of risk.

The USEPA concluded that the reregistration of naphthalene acetates were acceptable. These conclusions apply to the Canadian situation. Furthermore, the PMRA will require terrestrial buffer zones for naphthalene acetates to protect terrestrial plants from spray drift.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of naphthalene acetates, the PMRA is proposing further risk-reduction measures for product labels.

Human Health

- Protective equipment to protect mixer/loader/applicators

Environment

- Buffer zones to protect non-target, sensitive terrestrial habitats

Next Steps

Before making a final re-evaluation decision on naphthalene acetates, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Science Evaluation

1.0 Introduction

Naphthalene acetates are plant growth regulators due to their structural similarity to the natural plant growth hormone auxin, indole acetic acid. Auxin promotes growth in excised plant organs, induces adventitious roots, inhibits axillary bud growth, and regulates gravitropism. Naphthalene acetates are used to delay flower induction, prevent preharvest fruit drop, on orchard and on ornamental trees.

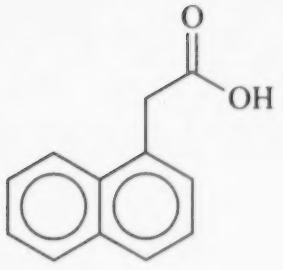
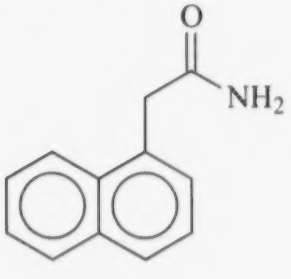
Following the re-evaluation announcement for naphthalene acetates, the registrant of the technical grade active ingredient and/or end-use products in Canada indicated that they intended to provide continued support for all uses included on the labels of commercial end-use products in Canada.

The PMRA used recent assessments of naphthalene acetates from the United States Environmental Protection Agency (USEPA). The USEPA Reregistration Eligibility Decision (RED) document for naphthalene acetates, dated October 2007, as well as other information on the regulatory status of naphthalene acetates in the United States can be found on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

2.0 The Technical Grade Active Ingredient, Its Properties and Uses

2.1 Identity of the Technical Grade Active Ingredient Naphthalene Acetates

Common Name	**Naphthalene Acetic Acid**	
Function	Plant Growth Regulator	
Chemical Family	Synthetic Auxins, Arylacetic acids	
Chemical Name		
1 **International Union of Pure and Applied Chemistry (IUPAC)**	1-naphthylacetic acid	
2 **Chemical Abstracts Service (CAS)**	1-naphthaleneacetic acid	
CAS Registry Number	86-87-3	1-naphthaleneacetic acid
Molecular Formula	$C_{12}H_{10}O_2$	1-naphthaleneacetic acid

Structural Formula	
Molecular Weight	186.2 amu
Purity of the Technical Grade Active Ingredient	98.5%
Registration Number	Technical grade active ingredient not currently registered Registered end-use products (Amvac): Reg. No. 14630 Fruitone (sodium salt) Reg. No. 16027 Fruit Fix Concentrate (ammonium salt)
Common Name	**Naphthalene acetamide**
Function	Plant growth regulator
Chemical Family	Synthetic auxins, arylacetic acids
1 IUPAC	2-(1-naphthyl)acetamide
2 CAS	1-naphthaleneacetamide
CAS Registry Number	86-86-2
Molecular Formula	$C_{12}H_{11}NO$
Structural Formula	

Molecular Weight	185.2 amu
Purity of the Technical Grade Active Ingredient	96% minimum
Registration Number	24971 (Amvac Chemical Corp.)

For naphthalene acetamide, based on the manufacturing process, the product is not expected to contain impurities of human health or environmental concern as identified in Regulatory Directive DIR98-04, *Chemistry Requirements for the Registration of a Technical Grade of Active Ingredient or an Integrated System Product*, Section 2.13.4, or TSMP Track 1 substances as identified in Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, Appendix II.

For naphthalene acetic acid, no technical ingredient is currently registered.

2.2 Physical and Chemical Properties of the Technical Grade Active Ingredient

Property	**Naphthalene Acetic Acid**
Vapour Pressure at 25°C	< 0.01 mPa
Solubility in Water at 20°C	420 mg/L (pH unspecified, data for acidic, neutral and basic pH required)
Dissociation Constant	3.16×10^{-4} (pKa = 3.50)

Property	**Naphthalene Acetamide**
Vapour Pressure at 25°C	1.98×10^{-8} Pa
Ultraviolet/Visible Spectrum	determined at pH <2, ~7, and >10: λ_{max} 223 nm ($\varepsilon \approx 75\,000$ L/(mol cm)) λ_{max} 280 nm ($\varepsilon \approx 6700$ L/(mol cm))
Solubility in Water at 20°C	170 ppm
***n*-Octanol–water partition coefficient at 25°C**	$\log K_{ow} = 1.58$
Dissociation Constant	Not applicable

2.3 Comparison of Use Patterns in Canada and the United States

Naphthalene acetates are plant growth regulators with auxin-like activity registered in Canada to delay flower induction, prevent preharvest fruit drop of apples, pears and ornamental crabapples.

They act by inducing formation of an abscission zone in the peduncle. Naphthalene acetates are applied at bloom for thinning or preharvest for preventing fruit dropping.
The American and Canadian use patterns were compared. The registered formulation type, use sites and maximum application rate for naphthalene acetates in Canada are also part of the American naphthalene acetates use pattern. Therefore, the assessments conducted in the USEPA RED are an adequate basis for the re-evaluation of uses of naphthalene acetates in Canada.

All current uses are being supported by the registrant and were, therefore, considered in the re-evaluation of naphthalene acetates. Appendix I lists the naphthalene acetates products that are registered as of 30 June 2008 under the authority of the *Pest Control Products Act*.

3.0 Impact on Human Health and the Environment

In their 2007 RED, the USEPA concluded that the end-use products formulated with naphthalene acetates met the safety standard under the American *Food Quality Protection Act* and would not pose unreasonable risks or adverse effects to humans and the environment if used according to the amended product labels.

3.1 Human Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

In Canada, exposure to naphthalene acetates may occur through consumption of food and water, through residential exposure, while working as a mixer/loader/applicator or by prematurely entering treated sites. When assessing health risks, the PMRA considers two key factors: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (e.g. children and nursing mothers).

3.1.1 Occupational Exposure and Risk Assessment

Occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies being used to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating safety factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects, but mitigation measures to reduce risk would be required.

Workers can be exposed to naphthalene acetates when mixing, loading or applying the pesticide and when entering a treated site to conduct activities such as scouting and/or handling of treated crops.

3.1.1.1 Mixer/Loader/Applicator Exposure and Risk

Among the scenarios assessed in the RED, the following two exposure scenarios were considered relevant to the Canadian situation.

- Mixing and loading for airblast application
- Applying liquid by airblast spray

Handler exposure analyses were performed using the Pesticide Handlers Exposure Database assuming baseline personal protective equipment (PPE), i.e. long-sleeved shirt, long pants, shoes plus socks, no respirator and a maximum naphthalene acetates application rate of 370 g a.e./ha. The endpoints the USEPA used in their assessments are summarized in Appendix II.

The USEPA reported acceptable short-term dermal MOEs (i.e. >100) for all occupational exposure scenarios, ranging from 130 to 170 000 and inhalation MOEs for all occupational exposure scenarios, ranging from 22 000 to 2 300 000. No additional mitigation measures were required with respect to occupational handler exposure. However, a long-sleeved shirt and long pants were required for all uses.

The RED adequately addressed exposure scenarios associated with the uses of products containing naphthalene acetates in Canada, and conclusions derived from the RED apply to the Canadian situation. Based on this, the PMRA requires workers to wear long pants and a long-sleeved shirt during mixing, loading, applying, cleaning and repair activities. The proposed label amendments are listed in Appendix III.

3.1.1.2 Postapplication Exposure and Risk

Based on the use pattern of naphthalene acetates, workers could be exposed to residues after the product is applied. The USEPA estimated the risk for workers performing postapplication activities in the treated areas.

- Irrigating, scouting, and hand weeding
- Hand harvesting, pruning, propping, training and thinning

Chemical-specific dislodgeable foliar residue and activity-specific transfer coefficients were used to analyze postapplication exposure from contact with treated foliage. Dislodgeable foliar residue represents dermal amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant. A transfer coefficient is a factor that relates worker exposure to dislodgeable residues. Transfer coefficients are specific to a given crop and activity combination (e.g. hand harvesting apples, scouting late season cotton) and reflect standard work clothing worn by adult agricultural workers. The postapplication risk assessment was based on an application rate of 123 g a.e./ha, a dislodgeable foliar residue of 20%, a dermal transfer coefficient of 1000 for irrigation, a scouting and weeding and dermal transfer coefficient of 3000 for harvesting,

pruning, propping and thinning. The postapplication inhalation exposure was assessed to be negligible due to dilution of vapour outdoors.

The resulting MOE for irrigation, scouting and weeding on the day of treatment was 11 000; the MOE for harvesting, pruning, propping, training and thinning on the day of treatment was 3500. They are above the USEPA target MOE of 100. Although the maximum application used in the assessment (123 g a.e./ha) is lower than the Canadian maximum application rate for pears (167 g a.e./ha). The USEPA MOEs are protective enough to account for the differences in application rates between the United States and Canada. Based on the acute toxicity of the active ingredient, the USEPA requires a restricted-entry interval of 48 hours for all naphthalene acetates agricultural use products.

The RED adequately addressed exposure scenarios associated with the Canadian uses of naphthalene acetates. There is no risk concern with respect to postapplication exposure. The PMRA requires no further mitigation measures.

3.1.2 Non-Occupational Exposure and Risk Assessment

3.1.2.1 Residential Exposure

Residential exposure is estimated using the MOE approach described in Section 3.1.1. The toxicological endpoints by the USEPA selected for assessment of risk from residential exposure are summarized in Appendix II.

In Canada, the only potential residential exposure would be homeowners entering the treated areas. The USEPA did not assess the risk to homeowners exposed via dermal and inhalation postapplication of naphthalene acetates because exposure is expected to be negligible based on the use pattern. It should be noted that homeowner postapplication activities in Canada are expected to be similar to those of field workers, i.e. pruning, propping, training and thinning, with a much shorter exposure duration. The USEPA estimated the MOE for workers harvesting, pruning, propping, training and thinning on orchard trees to be 3500 at day 0. Based on this, the PMRA requires no further mitigation measures with respect to residential exposure.

3.1.2.2 Exposure from Food and Drinking Water

Acute dietary risk is calculated considering the highest ingestion of naphthalene acetates that would be likely on any one day, using food consumption and food residue values. A statistical analysis allows all possible combinations of consumption and residue levels to be combined to estimate a distribution of the amount of naphthalene acetates residue that might be consumed in a day. A value representing the high end (95^{th} percentile) of this distribution is compared to the acute reference dose (ARfD), which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, acute dietary exposure is considered acceptable.

Chronic dietary risk is estimated by determining how much of a pesticide residue may be ingested with the daily diet and comparing this potential exposure to an acceptable daily intake, which is the dose at which an individual could be exposed over the course of a lifetime and expect no adverse health effects. The acceptable daily intake is referred to as the ADI in Canada, and, in the RED, it is expressed as the chronic population adjusted dose (cPAD). The ADI is based on a relevant endpoint from toxicology studies and on safety factors protective of the most sensitive subpopulation.

The acute and chronic dietary exposure and risk estimates resulting from intake of food with residues of naphthalene acetates were determined by the USEPA for the general population and various population subgroups. Tier I acute and chronic dietary risks were assuming 100% of the crops are treated.

The highest acute exposure to naphthalene acetates from food consumption was for children one to two years old, taking up 10% of the aPAD. The highest chronic exposure to naphthalene acetates from food consumption was also for children one to two years old, taking up 8% of the cPAD. Both acute and chronic dietary exposure estimates were found to be well below the USEPA's level of concern.

Drinking water exposure to pesticides can occur through surface and ground water contamination. The USEPA calculated screening level estimates of naphthalene acetates concentration in surface water and ground water. Unrefined acute peaks were 17.8 ppb and 0.001 ppb for surface and ground water, respectively. The chronic annual average was 0.98 ppb for surface water. These estimates were based on a maximum application rate of 370 g a.e./ha.

No cancer dietary exposure assessment was performed by the USEPA because carcinogenicity studies did not indicate a carcinogenic concern.

This assessment is considered to be relevant to Canada because it encompasses all potential dietary exposure sources based on the Canadian use pattern. The American tolerances used in the risk assessment were equal to Canadian maximum residue limits (MRLs) (i.e. 0.1 ppm general MRL). The modelled estimated drinking water concentration was based on worst-case scenarios encompassing the annual Canadian application amount. Therefore, the USEPA's assessment is considered applicable to the Canadian situation.

3.1.2.3 Aggregate Risk Assessment

Aggregate risk combines the different routes of exposure to naphthalene acetates (i.e. from food, water and residential exposures).

Acute and chronic aggregate risk assessments are comprised of contributions from food and drinking water exposures.

In their 2007 RED, the USEPA calculated the acute and chronic drinking water level of comparison based on the dietary exposure estimates, default body weights and water consumption figures. Acute and chronic modelled estimated drinking water concentrations for both surface water and groundwater were found to be significantly below the acute and chronic drinking water level of comparisons for all population subgroups. The USEPA concluded that the aggregate exposure to naphthalene acetates in food and water does not present a risk of concern. Overall, the USEPA aggregate risk assessment adequately addressed the Canadian aggregate exposure scenarios. Therefore, the USEPA aggregate exposure conclusions are considered applicable to the uses of naphthalene acetates in Canada.

3.1.3 Cumulative Effects

The USEPA has not determined whether naphthalene acetates have a common mechanism of toxicity with other substances or whether it shares a toxic metabolite produced by other substances. Therefore, it was assumed that naphthalene acetates do not share a common mechanism of toxicity with other substances, and a cumulative risk assessment was not required.

3.2 Environment

3.2.1 Environmental Risk Assessment

The USEPA reported that a foliar half-life dissipation study measured half-life was 1.4 days for naphthaleneacetic acid and 5.5 days for naphthalene acetamide. Naphthalene acetamide is probably susceptible to hydrolysis, and the end product is 1-naphthaleneacetic acid or 1-naphthaleneacetate ion. Half-lives in soil and water were estimated to be 15 days for naphthalene acetic acid and 38 days for naphthalene acetamide in both media, respectively. Half-lives in sediment were 60 days for naphthalene acetic acid and 150 days for naphthalene acetamide. Aerobic soil metabolism half-life was estimated to be 3.9 days. The estimated aerobic soil metabolism was 11.7 days, and anaerobic soil metabolism was 23.4 days. Based on the estimated K_{oc} value, naphthalene acetic acid is likely to be more mobile in soil than naphthalene acetamide. The estimated K_{oc} range for naphthalene acetic acid was 160–610, and naphthalene acetic acid is expected to have medium to low mobility in soil.

To assess the ecological risk of naphthalene acetates to terrestrial and aquatic non-target plants and animals, the USEPA calculated risk quotients based on appropriate toxicity endpoints and expected environmental concentrations (EECs) and compared the resulting risk quotients to corresponding levels of concern (LOCs).

Risk assessments for insects were not performed due to lack of toxicity data. The USEPA reported that some screening studies involving several terrestrial insect species indicated naphthalene acetates were unlikely to cause substantial adverse effects in insects. Therefore, the potential for naphthalene acetates to have adverse effects on insects was expected to be low.

Aquatic EECs were estimated using the generic expected environmental concentration model. Modelling was based on a single application per season and an application rate of 370 g a.e./ha. Acute and chronic risk quotients did not exceed LOC for fish (Bluegill sunfish and Trout) and aquatic invertebrates (*Daphnia magna* and *Tubifex tubifex*).

No marine/estuarine data were available. Based on data from fresh water organism tested, the USEPA concluded that the risks to marine and estuarine organisms (fish, aquatic invertebrates, and plants) are unlikely to be of concern.
For birds and mammals, EECs were calculated using models based on typical food consumption parameters by various species, following an application rate of 370 g a.e./ha. Acute risk quotients did not exceed the LOC for birds feeding on short grass, tall grass, small insects, fruits, etc. Although no chronic studies were available, the USEPA believed there were no substantial differences between the acute and chronic values based on mammal studies.

For terrestrial plants, EECs were calculated based on an application rate of 370 g a.e./ha, using models that estimate naphthalene acetates residues in areas adjacent to the treated field. The risk quotient for terrestrial plants did not exceed the LOC of 1.0 for terrestrial plants.

The USEPA believed that naphthalene acetates did not present significant potential risks to birds, mammals, fish, aquatic invertebrates, or aquatic plants. Conclusions derived from the USEPA RED are considered relevant to the Canadian situation.

The PMRA calculated terrestrial buffer zones using the most sensitive endpoints and a more conservative model to further minimize spray drift to non-target species during ground applications; proposed label amendments are listed in Appendix III. Inputs to buffer zone models are described in Appendix IV.

3.2.2 Toxic Substances Management Policy Considerations

The management of toxic substances is guided by the 1995 federal TSMP, which puts forward a preventive and precautionary approach to deal with substances that enter the environment and could harm the environment or human health. The policy provides decision makers with direction and sets out a science-based management framework to ensure that federal programs are consistent with its objectives. One of the key management objectives is virtual elimination from the environment of toxic substances that result predominantly from human activity and that are persistent and bioaccumulative. These substances are referred to in the policy as Track 1 substances.

The federal TSMP and PMRA Regulatory Directive DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, were taken into account during the re-evaluation of naphthalene acetates. The PMRA has reached the following conclusions.

- Naphthalene acetamide is not bioaccumulative. The *n*-octanol–water partition coefficients (log Kow) is 1.58 at 25°C, which is below the TSMP Track 1 cut-off criterion of ≥ 5.0.

- Naphthalene acetamide is not found to be persistent. Aerobic soil half-life is 38 days, which is below the TSMP Track 1 criterion of 180 days. Thus naphthalene acetamide is not a candidate for Track 1 classification.

- No other impurities of toxicological concern as identified in Regulatory Directive DIR98-04, Section 2.13.4, or TSMP Track1 substances as identified in Regulatory Directive DIR99-03, Appendix II, are expected to be present in the technical product of naphthalene acetamide.

Formulant issues are being addressed through PMRA formulant initiatives and Regulatory Directive DIR2006-02, *Formulants Policy and Implementation Guidance Document,* published on 31 May 2006.

4.0 Incident Reports

Starting 26 April 2007, registrants are required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Incidents are classified into six major categories including effects on humans, effects on domestic animals and packaging failure. Incidents are further classified by severity, from minor effects such as skin rashes, headache, etc., to major effects such as reproductive or developmental effects, life-threatening conditions or death.

The PMRA will examine incident reports and take appropriate measures when there are reasonable grounds to suggest that the health and environmental risks of the pesticide are no longer acceptable. These measures will range from minor label changes to discontinuation of the product.

As of 31 July 2008, there were no incident reports submitted for naphthalene acetates.

5.0 Proposed Re-evaluation Decision

The PMRA has determined that naphthalene acetates are acceptable for continued registration with the implementation of the proposed risk-reduction measures. These measures are required to further protect human health and the environment. The labels of Canadian end-use products must be amended to include the label statements listed in Appendix III. A submission to implement label revisions will be required within 90 days of finalization of the re-evaluation decision.

6.0 Supporting Documentation

PMRA documents, such as Regulatory Directive DIR2001-03, and DACO tables can be found on our website at www.pmra-arla.gc.ca. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798;
e-mail: pmra_infoserv@hc-sc.gc.ca.

The federal TSMP is available through Environment Canada's website at www.ec.gc.ca/toxics.

The USEPA RED document for naphthalene acetates is available on the USEPA Pesticide Registration Status page at www.epa.gov/pesticides/reregistration/status.htm.

List of Abbreviations

ADI	acceptable daily intake
a.e.	acid equivalent
bw	body weight
CAS	Chemical Abstracts Service
cPAD	chronic population adjusted dose
cRfD	chronic reference dose
DACO	data code
EC_{25}	exposure concentration to 25% (a concentration causing 25% adverse effects in the test population)
EEC	expected environmental concentration
g	gram(s)
ha	hectare
IUPAC	International Union of Pure and Applied Chemistry
kg	kilogram(s)
K_{oc}	organic carbon partition coefficient
K_{ow}	*n*-octanol–water partition coefficient
L	litre(s)
LOAEC	lowest observed adverse effect concentration
LOAEL	lowest observed adverse effect level
mg	milligram(s)
mm Hg	millimetre mercury
MOE	margin of exposure
MRL	maximum residue limit
NOAEL	no observed adverse effect level
PHI	preharvest interval
p*K*a	-log10 acid dissociation constant
PMRA	Pest Management Regulatory Agency
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
PRVD	Proposed Re-evaluation Decision
RED	Reregistration Eligibility Decision
REI	restricted-entry interval
RVD	Re-evaluation Decision
TC	transfer coefficient
TSMP	Toxic Substances Management Policy
USEPA	United States Environmental Protection Agency

Appendix I Registered Products Containing Naphthalene Acetates as of 30 June 2008

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee (%)
24971	Technical	Amvac Chemical Corporation	1-naphthaleneacetamide Technical	N/A	96% 1-naphthaleneacetamide
13167	Commercial	Amvac Chemical Corporation	Amid-thin	Wettable powder	8.3% 1-naphthaleneacetamide
14630	Commercial	Amvac Chemical Corporation	Fruitone N	Solid	3.1% 1-naphthalene acetic acid
16027	Commercial	Amvac Chemical Corporation	Fruit Fix Concentrate	Solution	5.2% 1-naphthalene acetic acid

Appendix II Toxicological Endpoints Selected by the USEPA for Naphthalene Acetates Health Risk Assessments

Exposure Scenario (Route and Period of Exposure)	Dose (mg/kg bw/day)	Study	Target UF/SF or MOE[a]
Acute Dietary All populations	NOAEL = 50 LOAEL = 250	Rat Developmental	UF = 100 *Food Quality Protection Act* safety factor = 1
Chronic Dietary All populations	NOAEL = 15 LOAEL = 75	Chronic Dog	UF = 100 *Food Quality Protection Act* safety factor = 1
Dermal Short-term (1–30 days)	NOAEL = 300 LOAEL = 1000	21-day Dermal Rat	UF = 100 *Food Quality Protection Act* safety factor = 1
Inhalation Short-term (1–30 days)	NOAEL = 50 LOAEL = 150	Oral Developmental Rat	UF = 100

[a] UF/SF refers to total of uncertainty factors and/or safety factors for dietary assessments. MOE refers to desired margin of exposure for occupational or residential assessments.

Appendix III Label Amendments for Products Containing Naphthalene Acetates

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

A submission to request label revisions will be required within 90 days of finalization of this re-evaluation decision.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) The following statements must be included in a section entitled **PRECAUTIONS**.

> Wear long pants, a long-sleeved shirt and shoes plus socks during mixing, loading, applying, cleaning and repair.

II) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS**.

> TOXIC to non-target terrestrial plants. Observe buffer zones specified under DIRECTIONS FOR USE.

III) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

> Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.
>
> **DO NOT** apply by air.
>
> **Buffer zones:**
>
> Use of the following spray methods or equipment DO NOT require a buffer zone: hand-held or backpack sprayer and spot treatment.
>
> The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, woodlots, hedgerows, riparian areas and shrublands).

Method of Application	Crop	Buffer Zones (metres) Required for the Protection of Terrestrial Habitat:
Airblast	Apples, pears	4
Airblast	Ornamental crabapples	2

Appendix IV Inputs to Buffer Zone Models

Ground Use Data (from Canadian labels)				
Crop	**Formulation Type**	**Method of Application**	**Number of Application**	**Maximum Application Rate (g a.e./ha)**
Apples	Wettable Powder	Ground Application	3	123
Pears	Wettable Powder	Ground Application	1	167
Ornamental crabapples	Wettable Powder	Ground Application	1	123

Model Input Data for Terrestrial Buffer Zones (from 2007 RED)		
Half-life for terrestrial buffer zones	Stable	99 999 999 days
Most sensitive terrestrial plant species EC_{25} for vegetative vigour	Tomato	48.31 g a.e./ha

References

Studies Considered in the Chemistry Assessment

List of Studies/Information Submitted by Registrant

PMRA Number	Reference
1610587	Technical Chemistry file NAD-CSV-1. NAD: Product Identity and Composition of 1-Naphthalene acetamide and Attachment 1, DACO 2.11 and DACO 2.13.4
1610586	Technical Chemistry file NAD-CSV-1. Additional data requested for 1-Naphthalene acetamide, DACO 2.13.3
1610597	Technical Chemistry file NAD-CSV-1. 1-Naphthalene acetamide - Vapor Pressure, DACO 2.14
1610612	Technical Chemistry file NAD-CSV-1. 1-Naphthalene acetamide - Ultraviolet-Visible Absorption Spectra, DACO 2.14
1610604	Technical Chemistry file NAD-CSV-1. 1-Naphthalene acetamide - Water Solubility, DACO 2.14
1610622	Technical Chemistry file NAD-CSV-1. 1-Naphthalene acetamide - Octanol/Water Partition Coefficient, DACO 2.14
1349365	NAA: Physical and Chemical Characteristics, DACO 2.14.10